UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MASSACHUSETTS

United States of America ex rel. Jeffrey J. Bierman, Plaintiff, v. Orthofix International N.V., et al., Defendants.	Civil Action No. 05-10557 (RCL)
United States of America ex rel. Marcus Laughlin, Plaintiff, v. Orthofix International, NV, Defendant.	(formerly Civil Action No. 1:08-cv-11336 (JLT))

MEMORANDUM IN SUPPORT OF DEFENDANT SMITH & NEPHEW, INC.'S MOTION TO DISMISS THE SECOND AMENDED AND SUPPLEMENTAL COMPLAINT OF RELATOR JEFFREY J. BIERMAN

Pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, Defendant Smith & Nephew, Inc. ("Smith & Nephew") submits this Memorandum of Law in support of its Motion to Dismiss the Second Amended and Supplemental Complaint ("SAC") of Relator Jeffrey J. Bierman. Smith & Nephew joins in and adopts the arguments stated in the Defendants' Joint Memorandum in Support of the Defendants' Motions to Dismiss the Second Amended and

Supplemental Complaint (except where noted therein[1]) and by this brief sets forth additional reasons why Bierman's claims against Smith & Nephew should be dismissed with prejudice.

BIERMAN'S CLAIMS AGAINST SMITH & NEPHEW MUST BE DISMISSED BECAUSE HE FAILS TO SATISFY THE REQUIREMENTS OF RULE 9(b)

The claims against Smith & Nephew in the SAC are primarily based on generalized allegations that the "Defendants," "Manufacturers" and "Companies" (presumably including Smith & Nephew, although Bierman rarely references Smith & Nephew by name) violated the False Claims Act ("FCA") in two ways. First, by directly submitting claim forms to the government allegedly representing that their osteogenic stimulation devices (i) should be paid as a purchase instead of a rental item, and (ii) are medically indicated for periods of time in excess of the medical needs of patients. SAC ¶¶ 4, 113-119. And second, by allegedly violating the Anti-Kickback Statute by providing free devices to physicians and paying independent sales agents a percentage of Medicare sales.[2] SAC ¶¶ 6, 120-123.

Although this iteration of Bierman's Complaint contains more factual detail and allegations against specific Defendants, Bierman still does not allege with the particularity required by Fed. R. Civ. P. 9(b) the time, place, and content of Smith & Nephew's alleged fraudulent scheme(s), the connection between any such scheme and any actual or planned false claims, and the particular false claims that Smith & Nephew allegedly either submitted or planned to submit to the government for payment. This requires that Bierman's claims against Smith & Nephew be dismissed in their entirety. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir.

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1 Smith & Nephew's device – Exogen – transmits low intensity ultrasound and is billed under CMS code E0760. The other Defendants' devices use electromagnetic fields and are billed under CMS codes E0747 and E0748. This difference is significant in this case, as shown below.

2 Bierman took more care in the SAC to name individual Defendants. Bierman explicitly excludes Defendant Orthologic from his Anti-Kickback Statute allegations. SAC ¶ 120. Bierman's sales agent claims apply only to Defendants Smith & Nephew, Orthofix and DJO. SAC ¶ 123(b)(ii). Bierman's third party supplier claims apply only to Defendants EBI, Orthofix and DJO. SAC ¶ 123(c)(i).

2007); *United States ex rel. Gagne v. Worcester*, 565 F.3d 40, 45-49 (1st Cir. 2009); *United States ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220, 232-5 (1st Cir. 2004).

I. Bierman's Allegations Against Smith & Nephew are not Supported by Facts

Out of the 406 paragraphs contained in the 125-page SAC, only 11 mention Smith & Nephew by name. Bierman has alleged nothing more against Smith & Nephew than vague generalizations of wrongdoing based on information allegedly provided to him[3] by unidentified sources. Although Bierman has supplemented the SAC with voluminous exhibits containing claim data, these records prove only that Smith and Nephew submits claims to Medicare in the ordinary course of its business. Bierman's failure to plead fraud with the requisite particularity, as well as his failure to connect an alleged fraudulent scheme to the submission of a single false claim, requires that the SAC be dismissed.

The only allegations that Bierman makes directly regarding Smith & Nephew are:

- Smith & Nephew's device – Exogen – heals by transmitting low intensity ultrasound to a patient's fracture site through the use of a coupling gel; it does not use electromagnetic fields. SAC ¶ 27.
- Smith & Nephew are the "sole manufacturers" of ultrasonic osteogenesis stimulators in the United States. SAC ¶ 28.
- Exogen has a "single power source . . . with a life of a minimum of 150 daily treatment periods (five months)." SAC ¶ 31.
- In a 2003 FDA Adverse Event Report, Smith & Nephew stated that the "type of device usage" for its bone growth stimulator is "reuse." SAC ¶ 46.

[3] Bierman, who is the co-owner of a small company in Missouri that provides billing services (less than half of which relate to DME), *see* SAC ¶ 9, never explains why he should be viewed as an "insider" or how he would have access to any information concerning the matters he alleges beyond that involving his local customer base.

- Smith & Nephew allegedly offered a "Limited Reimbursement Program" for its Exogen device where it would process a refund if x-rays demonstrated no progression to healing, and that the program "appears to have been discontinued." SAC ¶ 75. Bierman does not state the source of this information. *Id.*
- An unidentified Smith & Nephew sales representative allegedly told Bierman that Smith & Nephew devices were "always billed as a purchase," that the company – at some unidentified time – reclaimed devices to track healing times, although it no longer did that, and that the time of patient use is "usually about three months." SAC ¶ 86.
- An unidentified client of Bierman's allegedly told him that Smith & Nephew had a "personal courtesy unit program" where doctors provide free devices to indigent patients, which allegedly is designed to obtain unidentified doctors' business on an unspecified amount of billable units. SAC ¶¶ 99, 123(a)(i), (ii).
- An unidentified client of Bierman's allegedly told him that Smith & Nephew used to sell its product through a network of unnamed, independent distributors who are paid an unspecified percentage of the unspecified billings they generate and that the practice was allegedly discontinued in 2007. SAC ¶¶ 100, 123(b)(i), (ii).
- Data indicating that Smith & Nephew submitted claims to Medicare and Medicaid in the years 1994, 1995, 1996, 1997, 2001 and 2002. SAC ¶ 119, Exhibits A, B and C.[4]

These are the allegations that are notable for what they *do not* allege concerning Smith & Nephew:

[4] Importantly, although Bierman submitted Smith and Nephew Medicare claims for the years 1994, 1995, 1996, 1997, 2001 and 2002 in Exhibits A, B, and C to the SAC, Bierman explicitly states that "the allegations [in the SAC] do not apply to Smith & Nephew prior to 2001." SAC ¶ 27.

- All of the clinical studies that Bierman cites to support his claim regarding the appropriate length of use for the devices involve the use of ***electromagnetic*** fields, SAC ¶¶ 71-73; none involves ***ultrasound***, and so they do not pertain to or concern Exogen.
- Bierman's 22-month "sting operation" bore no fruit in terms of uncovering a single fraudulent act, or a single fraudulent claim submitted or caused to be submitted by Smith & Nephew. SAC ¶¶ 89-112.
- Bierman makes no allegation that Smith & Nephew engaged third-party suppliers who were allegedly granted volume discounts. SAC ¶ 123(c).
- There is no claim for damages that is specific to Smith & Nephew or attributed to Exogen. SAC ¶¶ 59, 124.

Finally, Bierman is unable to back up his generalized claims alleging behavior by the "Defendants," "Manufacturers" and the "Companies," with any factual allegations of Smith & Nephew wrongdoing. Bierman provides ***no facts*** to support allegations that Smith & Nephew:

- Misleads physicians and their clerical staff into filling out CMNs indicating that the devices are medically necessary for the patient's lifetime or for periods that exceed the needs of the patient and/or the devices' useful life. SAC ¶ 36.
    - In fact, Bierman concedes that Exogen did not require a CMN ***prior*** to 2007, and he fails to provide any evidence of claims submitted by Smith & Nephew ***after*** 2007. SAC ¶ 5 fn. 2 and ¶ 35; ***see also*** Exhibits A, B and C. Therefore, by definition, Smith & Nephew is excluded from Bierman's allegation that a fraudulent scheme existed whereby Defendants "cause[d] physicians, their employees and/or clinicians to include false information on CMNs." SAC ¶ 5.
- Routinely violates supplier standards. SAC ¶ 49.

- Forces Medicare patients to bear the burden of unnecessarily high co-pays. SAC ¶ 50.
- Got together with other manufacturers to block reclassification of the devices. SAC ¶ 91.

The particularity requirement of Rule 9(b) exists because the mere accusation of fraud often causes harm. *Rost*, 507 F.3d at 733 (internal citations omitted). As set forth in more detail below, Bierman has failed to meet the threshold particularity requirements of Rule 9(b) and on that basis, the SAC should be dismissed as to Smith & Nephew.

II. Bierman Does Not Allege That Smith & Nephew Submitted Or Planned To Submit Specific False Claims

The submission of an actual false claim is the "sine qua non" of a FCA violation under § 3729 (a)(1). *Karvelas*, 360 F.3d. at 225. This – coupled with the strictures of Rule 9(b) – requires Bierman to allege with particularity the false or fraudulent claims that Smith & Nephew submitted or caused to be submitted to the government for payment. *Id.* Specifically, he must provide some specific information about the content of the false claims, such as dates of the false claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved with the billing, the length of time between the alleged fraudulent practices, and the submission of claims based on those practices. *Karvelas*, 360 F.3d. at 233.[5]

Section § 3729 (a)(2) requires that Bierman allege a "double-falsehood," i.e. that each defendant made or used or caused to be made or used a *false record or statement* in order to get a *false or fraudulent claim* paid by the government. *See United States of America ex. rel. Franklin v.*

[5] Bierman will undoubtedly argue that his claim survives under the alternate Rule 9(b) standard the First Circuit articulated in *Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 12 (1st Cir. 2009). However, this standard only applies when a plaintiff alleges that a defendant has induced *third parties* to file false claims with the government. *Id.* at 29. Consequently, *Duxbury* does not apply to this case because Bierman's allegations regarding the manner in which Smith & Nephew is reimbursed make it clear that it bills Medicare directly for its devices.

Parke-Davis, 2003 U.S. Dist. LEXIS 15754 at *3-4 (D. Mass. August 22, 2003)*; Gagne*, 565 F.3d at 46 n. 7. Rule 9(b) requires that Bierman allege each prong of this double falsehood – the false record or statement and the false or fraudulent claim – with particularity, even if the false claim involved is only a *planned* false claim. *See Gagne*, 565 F.3d at 46 n. 7; *United States ex rel. Lacy v. New Horizons, Inc.*, 2009 U.S. App. LEXIS 22294 at *15-17 (10th Cir. October 9, 2009).

Despite the fact that Bierman has added factual allegations to the SAC and submitted voluminous exhibits in support of his claims, he still fails to allege the specifics of any particular *false* claim that Smith & Nephew submitted, caused to be submitted, or planned to submit to the government as a result of or in connection with any of the purported fraudulent schemes that Bierman alleges generally. Moreover, the SAC fails to allege either the total number of devices, the total amount of false claims, or the total amount of damages for which Smith & Nephew is responsible. The chart in paragraph 59 of the SAC that purports to show Medicare reimbursements totaling $429 million between 1998 and 2008 is entirely devoid of Smith & Nephew data. *See* SAC ¶ 59. This is for two reasons, which Bierman concedes. *Id.* First, Smith & Nephew's device was not covered by Medicare until 2001, and second, "the E0760 device was not in the Top 200 for the time period 2001 through 2008" and on that basis, even Medicare *itself* did not report the figures for Smith & Nephew's device. *Id.*

Notably, Bierman has not specified any false claims or damages that arise out of Smith & Nephew's alleged fraud. In alleging damages, he states that "[b]etween 1998 and 2008 Medicare paid approximately $400 million for osteogenesis stimulators." SAC ¶ 124. However, this $400 million figure is slightly *less* than the $429 million Bierman alleges earlier in the SAC to be the *total* amount charged to Medicare for *electromagnetic* devices, which, by definition, includes no ultrasound devices manufactured by Smith & Nephew. SAC ¶ 59.

Even Exhibits A, B and C, which include Smith & Nephew Medicare claims for the years 1994, 1995, 1996, 2001 and 2002 do not get Bierman over the hurdle of the 9(b) particularity requirement. Further, his inclusion of claims data for the years prior to 2001 is a red herring, because as Bierman points out, "The Exogen Bone Healing System has been covered by Medicare since 2001. The allegations herein do not apply to Smith & Nephew prior to 2001." SAC ¶ 27 (emphasis added). Because he has not either alleged Smith & Nephew's underlying fraudulent conduct with particularity, or sufficiently alleged that such behavior caused the filing of false claims, these Exhibits do not demonstrate that Smith & Nephew filed a single *false* claim with Medicare.

III. Bierman Does Not Allege Smith & Nephew's Underlying Fraudulent Conduct With The Specificity Required By Rule 9(b)

Not one of the allegations in the SAC provide "who, what, where, and when" of the allegedly fraudulent conduct that a relator such as Bierman ***must*** allege in order to comply with Rule 9(b) and survive a motion to dismiss. *Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 12 (1st Cir. 2009). For example, Bierman alleges that Smith & Nephew has violated the Anti-Kickback Statute by providing doctors with free devices, and paying independent sales agents a percentage of Medicare sales. SAC ¶¶ 6, 120-123. But the "support" for these allegations is nothing more than statements attributed to unidentified individuals and blanket statements that Defendants violated the Anti-Kickback Statute. *Id.*

Bierman does not provide the names of the physicians who supposedly received the free devices from Smith & Nephew as part of its "professional courtesy unit" program; information regarding particular prescriptions for Exogen written as a result of these free devices; examples of how payments to independent sales agents influenced claims submitted to the government for reimbursement; the amount, date, or method of any payments made as part of any of these alleged

schemes; or the names of any individuals that participated in any of the alleged conduct. In sum, he provides nothing that links Smith & Nephew to any particular false statement, statutory violation, or false claim.

IV. Bierman Does Not Allege A Connection Between Smith & Nephew's Allegedly Fraudulent Conduct And The Submission Or Planned Submission Of A False Claim

In order to survive a motion to dismiss, Bierman must specify "the time, place and content" of the alleged fraudulent scheme, the connection between that scheme and the false claims, and the details that identify the particular false claims. *See Rost*, 507 F.3d at 731; *Gagne*, 565 F.3d at 45-49; *Karvelas*, 360 F.3d. at 232-5. But since he has pleaded neither a fraudulent scheme nor an actual or planned false claim with the particularity required by Rule 9(b), he cannot plead – and has not plead – a connection between those two crucial elements with the required particularity. Even his 22-month "sting operation" failed to uncover either fraudulent acts by Smith & Nephew, or false claims caused to be submitted by such acts. Bierman's failure to connect Smith & Nephew's allegedly fraudulent acts to the submission or planned submission of a false claim is yet another reason to dismiss Bierman's claims against Smith & Nephew in their entirety.

CONCLUSION

Rule 9(b)'s particularity requirement exists because "[i]t is a serious matter to accuse a person or company of committing fraud, and the mere accusation often causes harm." *Rost*, 507 F.3d at 733. It is therefore important to discourage plaintiffs from filing generalized and unsupported allegations of fraud in the hopes of conducting embarrassing discovery or forcing a settlement. *Id., citing New England Data Services, Inc. v. Becher*, 829 F.2d 286, 288 (1st Cir. 1987). The particularity requirements of Rule 9(b) are especially appropriate for FCA claims brought by relators such as Bierman because, by their very nature as "insiders," they should have adequate knowledge of the wrongdoing at issue and be able to comply with Rule 9(b). *Bly-Magee*

v. California, 236 F.3d 1014, 1019 (9th Cir. 2001); *United States of America ex rel. Ondis v. City of Woonsocket, et al.*, 2009 U.S. App. LEXIS 25298 at *14-5, 19 (1st Cir. November 18, 2009). ("Congress designed the FCA to encourage[e] lawsuits by relators who have firsthand knowledge of fraud against the government . . . [t]o achieve its real purpose, the FCA should reward only those who come forward with original, direct, and independent knowledge of a fraud.").

Bierman's claims against Smith & Nephew are a handful of vague, declaratory statements of wrongdoing that fail to satisfy even the most basic level of specificity. Bierman simply alleges that Smith & Nephew violated the FCA and then expects this Court to accept that because Bierman states that Smith & Nephew defrauded the government, it must be so. This goes against both the spirit and the letter of Rule 9(b), and requires that Bierman's claims against Smith & Nephew be dismissed in their entirety.

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Dated: August 17, 2010

Certificate of Service

I hereby certify that this Memorandum in Support of Defendant Smith & Nephew, Inc.'s Motion to Dismiss the Second Amended and Supplemental Complaint of Relator Jeffrey J. Bierman filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on August 17, 2010 and to all non-registered participants by United States mail, first class, postage prepaid.

/s/ Christine Vargas Colmey
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